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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,493	06/24/2005	Dominique Giorgi	1169-036	7207

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1652	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,493	GIORGI ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-61* is/are pending in the application.

4a) Of the above claim(s) *28-55,57 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56,58,60 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 June 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to restriction requirement

Applicants' election with traverse of Invention XV, **Claims 56 and 58** and the further election of SEQ ID NO: 1 in amendment, filed April 2, 2007 is acknowledged. The traversal is on the ground(s) that the Examiner has not shown how WO 02/070539 causes PCT Rules 13.1 and 13.2 to be unsatisfied. Specifically, there is no showing as to how WO 02/070539 renders the claimed subject matter to not be a "contribution over the prior art."

This is not found persuasive because WO 02/070539 discloses amino acid sequences and fragments that are at least 80% identical to the amino acid sequence of SEQ ID NO: 1(see rejection of claims under 35 U.S.C 102(b) below).

Therefore the requirement is still deemed proper and is made FINAL. **Claims 1-27** have been canceled. **Claims 59-61** have been added. **Claims 28-61** are pending in this application. **Claims 28-55, 57 and 59** are withdrawn from further consideration because these Claims are drawn to non-elected inventions. **Claims 56, 58 and 60-61** are currently under examination.

Priority

The current application filed on June 24, 2005 is a 371 of PCT/FR03/03895, 12/24/2003, which in turn claims priority to foreign application, FRANCE 02/16648 filed on 12/24/2002. A certified copy of foreign document FRANCE 02/16648 has not been provided.

Preliminary Amendment

The preliminary amendment filed June 24, 2005 has been entered.

Drawings

Drawings filed June 24, 2005 have been objected to because the resolution of the Figures is extremely low, specifically Figure 2, wherein the picture of the electrophoresis gel is completely un-viewable.

Information Disclosure Statement

The IDS filed June 24, 2005 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 35, lines 11-14; page 37, lines 13-14; page 39, lines 36-37). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The specification is also objected to because there is no Brief Description of the Drawings in specification of the instant application.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56, 58 and 60-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of screening substance capable of modulating the activity of functional derivatives having at least 80% or 90% identity to SEQ ID NO: 1. The claims do not require that the polypeptide possess any particular conserved structure, or other distinguishing feature, such as a specific biological activity. Thus, the claims are drawn to a genus of polypeptides that is defined by an unclear functional relationship to SEQ ID NO: 1. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a partial structure in the form of a recitation of percent identity. The specification does not identify any particular portion of the structure that must be characteristics of the claimed genus are not described. The only adequately described species is SEQ ID NO: 1 and no active variants are disclosed. Accordingly, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the a14 that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not it clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116), As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers* v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird,* 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF' s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only SEQ ID NO: 1, but not the full breadth of the claim meets the written description provision of 35 U. S.C. 112, first paragraph. Applicant is reminded that *Vas-cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision.

Claims 56, 58 and 60-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 56** applicants have recited the phrase "a substance capable of modulating activity of a protein"; however applicants have not clarified what type of modulating is to occur- for example is the modulating of inhibitory nature?

Furthermore in **claim 56** applicants need to spell out "ASAP" in the first instance of use. **Claims 58 and 60-61** are dependent claims that do not overcome the deficiencies of the independent claim that they are dependent therefrom.

Also in **claim 56** applicants need to be consistent in the manner, which they refer to sequence identity, in another words "90% similarity" in line 4 of the claim should be amended to 90% identity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56, 58 and 60-61 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/070539 (cited in the IDS filed June 24, 2005).

WO 02/070539 discloses an amino acid sequence that is 99.5% identical to the amino acid sequence of SEQ ID NO: 1 (see sequence alignment performed by STIC attached to this Office Action in cited in the PTO-892).

WO 02/070539 teaches a method for detecting the polypeptides of the invention in a sample comprising contacting the sample with a compound that binds to and forms a complex with the polypeptide under conditions and for a period sufficient to form the complex and detecting the formation of the complex such that if a complex is formed, the polypeptide is detected (page 5, lines 19-24).

WO 02/070539 also teaches methods for the identification of compounds that modulate (i.e., increase or decrease) the expression or activity of the polypeptides of the invention and that such methods can be utilized, for example, for the identification of compounds that can ameliorate symptoms of disorders as recited herein. Such methods can include, but are not limited to, assays for identifying compounds and other substances that interact with (e.g., bind to) the polypeptides of the invention (page 5, lines 29-35).

WO 02/070539 teaches further that the invention provides a method for identifying a compound that binds to the polypeptides of the invention
I comprising contacting the compound with a polypeptide of the invention in a cell for a time sufficient to form a polypeptide/compound complex, wherein the complex drives expression of a reporter gene sequence in the cell; and detecting the complex by detecting the reporter gene sequence expression such that if expression of the reporter gene is detected the compound the binds to a polypeptide of the invention is identified (page 6, lines 1-5).

WO 02/070539 teaches that the purified polypeptides can be used in in vitro binding assays which are well known in the art to identify molecules which bind to the

polypeptides. These molecules include but are not limited to, for e.g., small molecules, molecules from combinatorial libraries, antibodies or other proteins. The molecules identified in the binding assay are then tested for antagonist or agonist activity in in vivo tissue culture or animal models that are well known (page 31, lines 29-35).

WO 02/070539 also teaches that the invention also provides chimeric or fusion proteins. As used herein, a "chimeric protein" or "fusion protein" comprises a polypeptide of the invention operatively linked to another polypeptide. Within a fusion protein the polypeptide according to the invention can correspond to all or a portion of a protein according to the invention. In one embodiment, a fusion protein comprises at least one biologically active portion of a protein according to the invention. In another embodiment, a fusion protein comprises at least two biologically active portions (page 34, lines 28-34).

Thus WO 02/070539 et al. teach all the elements of **claims 56, 58 and 60-61** these claims are anticipated under 35 USC 102(b).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
Art Unit 1652

Robert B Mondesi
6-15-2007